UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,124	01/12/2004	Andrew L. Abrams	MICRODOSE 99.02 CON2	3144

27667 7590 09/11/2007

HAYES SOLOWAY P.C.
3450 E. SUNRISE DRIVE, SUITE 140
TUCSON, AZ 85718

EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
09/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/756,124	ABRAMS ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *3 and 5-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *21-23* is/are allowed.

6)☐ Claim(s) *5-12 and 17* is/are rejected.

7)☐ Claim(s) *3,13-16 and 18-20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/18/07 has been entered.

Claim Objections

Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 3 is recited to depend in claim 24. However, there is no claim 24 in the amendment filed 06/18/07, or in this application. For examining purpose, claim 3 is interpreted to depend in claim 23.

Claim Rejections - 35 USC § 103

Claims 5, 8 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mlodozeniec et al. US 4,069,084, in view Trudell et al. US 5,207,705, and Lerner et al. US 6,197,331 or Inoue et al. US 4,772,470.

Mlodozeniec teaches a novel dosage form comprising an edible web having deposited thereon a particulate medicament or mixture of incompatible medicaments

alternatively between sheets (abstract; and column 4, lines 30-62). Medicaments are deposited on the web in dry powder form (columns 15-16). Medicaments are deposited on the web in fixed unit dose (column 4, lines 29-62). The dosage form offers any desired release pattern including sustained release (column 5, lines 5-53).

Mlodozeniec does not expressly teach release at two or more different selected sites. However, it is well known in pharmaceutical art that sustained release does provide release rate at various places in the GI tract. To be more specific, see Trudell for the teaching that sustained release is used to deliver different active compounds at different rates to different sites in the GI tract (column 9, lines 7-18). Thus, it would have been obvious to one of ordinary skill in the art to modify the dosage form of Mlodozeniec in view of the teaching of Trudell to obtain the claimed invention, because Trudell teaches a sustained release vehicle is useful to provide any release pattern, and because Mlodozeniec teaches the desirability of formulating a sustained release vehicle.

Mlodozeniec further does not teach an adhesive on an outer surface of the membrane.

Lerner teaches an oral patch composition comprising drug-containing layer, and an adhesive layer (abstract; and column 9, lines 12-67). The patch is useful for application to the teeth, and oral mucosa (column 13, lines 12-17).

Inoue teaches an oral bandage comprising a drug-containing layer, and an adhesive layer (abstract; column 8, lines 62-65; and column 9, lines 64 through column 10, lines 1-64).

Thus, it would have been obvious to one of ordinary skill in the art to modify the novel dosage form of Mlodozeniec to contain an adhesive layer in view of the teachings of Lerner or Inoue, because Lerner teaches the use drug loaded sheets for controlled release of drugs, because Inoue teaches an oral bandage formulation having excellent adhesion of long duration (column 10, lines 32-60), and because Mlodozeniec teaches a drug loaded web that is advantageous for a wide variety of controlled release oral dosage forms.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mlodozeniec et al., in view of Trudell et al. and Sanso US 6,350,468, and Lerner et al. or Inoue et al.

Mlodozeniec is relied upon for the reasons stated above. Mlodozeniec does not teach the combination of drugs in claims 17 and 21.

Sanso teaches a single unit dosage form comprising two different active ingredients being separated from one another by a membrane (see abstract). Combinations of active ingredients include omeprazole and clarithromycine (column 2, lines 15-32; and claims). Thus, it would have been obvious to one of ordinary skill in the art to modify the dosage form of Mlodozeniec for the combination of omeprazole and clarithromycine to obtain the claimed invention, because Mlodozeniec teaches a novel dosage form for a wide variety of drugs, because Mlodozeniec teaches a novel dosage form that is suitable for combination of two or more incompatible drugs, and because

Sanso teaches combination of omeprazole and clarithromycine that is useful in pharmaceutical art.

Claims 5-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sturzenegger et al. US 4,197,289, in view of Mlodozeniec et al. US 4,069,084 and Trudell et al.

Sturzenegger teaches a sustained release pharmaceutical dosage form comprising edible web having two or more medicaments electrostatically deposited onto the web that is self destructs or degradable in body fluids or enzymes (see abstract, columns 6-8, and columns 24-26). Before the deposit of the medicaments, the web can be coated with an adhesive layer (column 17, lines 5-41). The web can be processed into separate tablet layers, capsules, dragees, or suppositories (column 3, lines 38-41; and column 4, lines 58-60).

Sturzenegger does not expressly teach the fixed unit dose quantities of the medicaments.

Mlodozeniec teaches a novel dosage form comprising an edible web having deposited thereon a particulate medicament or mixture of incompatible medicaments alternatively between sheets (abstract; and column 4, lines 30-62). Medicaments are deposited on the web in dry powder form (columns 15-16). Medicaments are deposited on the web in fixed unit dose (column 4, lines 29-62). The dosage form offers any desired release pattern including sustained release (column 5, lines 5-53). Thus, it would have been obvious for one of ordinary skill in the art to modify the dosage form of

Sturzenegger to contain a fixed unit dose of drugs in view of the teaching of Mlodozeniec, because Sturzenegger teaches the exact and uniform deposition of the active ingredient on the web (column 11, lines 1-5), because Sturzenegger teaches the amount of active ingredient loaded can be determined by transmission spectrophotometry (column 12, lines 46-56), because Sturzenegger teaches the advantageous results of a single dosage form containing two or more medicaments being separated by edible membrane, and because Mlodozeniec teaches a novel dosage form containing edible web having deposited thereon a fixed dose of active ingredients that exhibits many advantageous results over the conventional dosage forms (columns 3-4).

It is noted that Sturzenegger does not expressly teach release at two or more different selected sites. However, it is well known in pharmaceutical art that sustained release does provide release rate at various places in the GI tract. To be more specific, see Trudell for the teaching that sustained release is used to deliver different active compounds at different rates to different sites in the GI tract (column 9, lines 7-18). Thus, it would have been obvious to one of ordinary skill in the art to modify the dosage form of Sturzenegger in view of the teaching of Trudell to obtain the claimed invention, because Trudell teaches a sustained release vehicle is useful to provide any release pattern, and because Sturzenegger teaches the desirability of formulating a sustained release vehicle suitable for delivery two or more different active compounds.

Claims Allowable

Claims 13-16 and 18-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 21-23 are allowed.

Response to Arguments

Applicant's arguments filed 06/18/07 have been fully considered but they are not persuasive.

Applicant argues that claim 5 has been amended to specify that the release sites are a stomach or intestines of a patient's alimentary canal, and that the adhesive comprises a mucosal adhesive layer. Lerner cited as teaching a drug-containing patch having an adhesive is designed for adherence to hard tensile surfaces such as teeth and dentures, and releases active pharmaceutical agents into the oral cavities. Thus, no combination of the art applied against claim 5 reasonably could be said to achieve or render obvious claim 5, or the several claims dependent thereon.

In response to applicant's argument, it is noted at column 3, lines 13-17, Lerner teaches sites of application include but are not limited to upper teeth, but also include oral mucosa of the mouth and throat, systemic delivery via the oral mucosa.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S. Tran
Primary Examiner
AU 1615